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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,808	03/15/2000	Athanasius A Anagnostou	5218-39C	9764

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/525,808	Applicant(s) ANAGNOSTOU ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,22,31-33 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,22,31-33 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Anagnostou et al

1. The amendment filed 10/31/2005 is acknowledged and entered into the record.
2. Accordingly, claims 1-15, 17-21,23-30, and 34-40 are canceled without prejudice or disclaimer, claims 41-43 are newly added.
3. Claims 16,22,31-33, and 41-43 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. The Information Disclosure Statement filed 10/31/2005 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained – 35 USC §102

6. The rejection of claims 16 and 31-33 under 35 USC 102(b) as being anticipated by Silvestris et al (Ann. Hematol. 1995 Jun.;70(6):313-318, previously cited) is maintained for the reasons of record. Applicant's provide a declaration by Dr. Sigounas which presents in vivo data regarding the protective or reparative effects of erythropoietin (EPO) on chemotherapeutically damaged endothelial cells. Applicant also argues that the cited reference does not teach an "endothelial-protecting amount of EPO" as claimed, specifically the administration of EPO "prior to receiving chemotherapy." Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

In the instant case, the claims as currently amended do not specifically limit the administration of EPO to patients prior to a chemotherapeutic regimen as argued. The claims only require that an "endothelial-protecting amount" be administered to patients with endothelial cells damaged by chemotherapy. As indicated in the previous office action, it is an inherent property of chemotherapeutics to damage the endothelial cells (see de Vos et al) and therefore, the population of patients receiving EPO treatment for multiple myeloma as disclosed by Silvestris et al would encompass treating those patients with damaged endothelial cells. Moreover, the Silvestris et al also teaches that some patients were undergoing "second-induction" chemotherapy and would therefore possess endothelial cells that have been already damaged by chemotherapy. Therefore, the administration of EPO, although conveyed by Silvestris et al for use in a different purpose, would inherently treat those patients undergoing additional chemotherapy, thereby meeting the limitation of "prior" to chemotherapy as claimed.

A declaration filed under 37 CFR § 1.132 cannot be used to overcome 102(b) rejection because it is a statutory bar. In the instant case, applicants have not provided any amendments to overcome what appears to be the same or identical method of treating patients with EPO as claimed. The declaration of provided by Dr. Sigounas discloses information regarding the use of EPO "prior" to the administration of chemotherapeutics. Specifically, Dr. Sigounas indicates that prior to the instant invention, those of skill in the art would not administer EPO before the treatment with chemotherapeutics, instead the skilled artisan would only administer EPO following the diagnosis of anemia. The declaration has been carefully considered but is not deemed

persuasive to overcome the rejection of record. The claims as currently presented do not preclude the administration of EPO to patients after chemotherapy as argued and presented. Therefore, the declaration is not commensurate in scope to what is being claimed.

Therefore, the rejections of claims under 35 USC 102(b) as being anticipated by Silvestris *et al* is maintained for the reasons of record.

Claim Rejection Maintained – 35 USC 102

7. The rejection of claims 16, 22,31-33, and now newly added claims 41-43 under 35 USC § 102(b) as being anticipated by JP 02 096535 (Chugai Pharm. Co. LTD, previously cited) is maintained for the reasons of record. Applicant's arguments are identical to those previously presented and rebutted above (see paragraph 5).

Applicants have not specifically addressed the issues pertinent to the prior art cited (applicant responds to rejections under a single heading of 102 and 103 rejections). As such, applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Therefore the rejection of claims under 35 USC 102(b) as being anticipatd is maintained for the reasons of record.

Claim Rejection Maintained – 35 USC 102

8. The rejection of claims 16,31-33 under 35 USC § 102(b) as being anticipated by Bukowski *et al* (Blood 1994;84(10 Supp. 1):129A, IDS #3 9/2/2003), previously cited) is maintained for the reasons of record. Applicant's arguments are identical to those

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previously presented and rebutted above (see paragraph 5). Applicants have not specifically addressed the issues pertinent to the prior art cited (applicant responds to rejections under a single heading of 102 and 103 rejections). As such, applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Therefore the rejection of claims under 35 USC 102(b) as being anticipatd is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

9. The rejection of claims 16,22,31-33, and now newly added claims 41-43 under 35 USC § 103(a) as being obvious over Silvestris *et al* or Bukowski *et al* in view of JP 02 096535 to Chugai Pharm. Co. LTD is maintained for the reasons of record.

Applicant's arguments are identical to those previously presented and rebutted above (see paragraph 5). Applicants have not specifically addressed the issues pertinent to the prior art cited (applicant responds to rejections under a single heading of 102 and 103 rejections). As such, applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

It is also noted that applicants have provided evidence (i.e. Sigounas Declaration) that presents "unexpected" results. When considering such evidence, the evidence set forth must be commensurate in scope. In the instant case, applicants present an animal model wherein a dosage of 60 U/kg was administered to the animal prior to the administration of a chemotherapeutic agent. However, the claims of the

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instant invention encompass a range beyond what is provided in the declaration.

Moreover, the claims do not specifically limit the administration of EPO prior to the administration of a chemotherapeutic agent.

Newly added claims 41-43 are deemed obvious because the cited reference teaches concomitant chemotherapy regimens and thus the administration of the EPO is considered prior to or after cisplatin administration. Moreover, the combination of the the cited reference specifically discloses the dosage range of EPO (see for example JP 02 096535 page 9, translation), because the dosage amount is less than 750 U/kg, specifically, 500 U/day).

Therefore the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
March 20, 2006


CHRISTOPHER YAEN
PATENT EXAMINER